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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,855	03/28/2001	Shlomo Berliner	00/21527	1641

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EXAMINER

CHOOBIN, BARRY

ART UNIT PAPER NUMBER

2625

DATE MAILED: 02/13/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,855

Applicant(s)

BERLINER, SHLOMO

Examiner

Barry Choobin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 63 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 63-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.
2. Applicant's election without traverse of claims 1-62 in Paper No. 4 is acknowledged.

Drawings

3. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color.

Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-13,15-29,31-38,40- 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasdan in view of applicant's admitted prior art.

As to claim 1, Kasdan discloses a system for generating a profile of particulate components of a body fluid sample comprising: (a) a device for causing controlled flow of the body fluid sample on a substrate (column 1, lines 24 – 26), said controlled flow of the body fluid sample leading to a differential distribution of the particulate components on said substrate (although Kasdan is silent about controlled flow of the body fluid sample leading to a differential distribution of the particulate components on said substrate. But applicant's background invention discloses this feature as well known in

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the art); and (b) a magnifying device being for providing a magnified image of differentially distributed particulate components on said substrate (column 2, lines 58-66), said magnified image representing a profile of said particulate components of the body fluid sample (column 2, lines 30-34).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the feature as though by applicant's prior art about controlled flow of the body fluid sample leading to a differential distribution of the particulate components on said substrate with the method of Kasdan in order to improve the assessment of a patient's overall health (refer to applicant's background section pages 1-2).

As to claim 2, Kasdan discloses an imaging device being for capturing said magnified image provided by said magnifying device (fig.1)

As to claim 3, Kasdan discloses imaging device is a camera (column 2, lines 58-67).

Claims 4, 10, 12, 13, 15, 16, 19-21, 23, 26, 28, 29, 31, 32, 35, 37-38, 45-46, 48-52 are similarly analyzed and rejected.

As to claims 6-9, 11, 17-18, 20, 22, 24-25, 27, 33, 34, 36, 44, 47, 53, the Examiner takes Official Notice.

As to claims 14 and 30, features included in claims 14 and 30 are inherent when a particulate component in a body fluid sample is determined.

Claim Rejections - 35 USC § 102

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasdan (US 5,822,447).

As to claim 54, Kasdan discloses a method of generating a profile of a body fluid sample comprising the steps of: (a) causing controlled flow of the body fluid sample on a substrate (column 1, line 62 – column 2, line 14), said controlled flow of the body fluid sample leading to a distribution of the body fluid sample on said substrate (column 2, lines 15-34); and (b) determining a thickness variance of the body fluid sample along a direction of said controlled flow on said substrate (column 2, lines 15-34), said thickness variance representing a profile of the body fluid sample (column 2, lines 30-34).

As to claim 55, Kasdan discloses the step of analyzing and optionally characterizing particulate components of said body fluid sample in at least one specific region of said substrate (column 2, lines 13-15).

As to claim 56, Kasdan discloses step of analyzing and optionally characterizing particulate components in said body fluid sample is effected according to at least one parameter selected from the group consisting of estimated hemoglobin concentration,

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approximated leukocyte count and differential, approximated platelet count, degree of leukocyte aggregation, aggregate composition, degree of leukocyte, erythrocyte and/or platelet adherence towards the surface of said substrate, degree of red cell aggregation, degree of platelet aggregation, degree of leukocyte to erythrocyte interaction, degree of erythrocyte to platelet interaction and degree of leukocyte to platelet interaction (column 2, lines 1-5).

Claims 57-58 are similarly analyzed and rejected.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 39, 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasdan and in view of Dietz et al (US 6,687,395).

As to claim 59, Kasdan discloses the method of claim 56 (see claim 56).

However, Kasdan is silent about clinical condition is caused by an

agent selected from the group consisting of an infective agent and a chemical agent.

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But on the other hand, Dietz et al disclose a system for micro volume laser scanning cytometry comprising: clinical condition is caused by an agent selected from the group consisting of an infective agent and a chemical agent (column 6, lines 55-67).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide the clinical condition is caused by an agent selected from the group consisting of an infective agent and a chemical agent as thought by Dietz et al with the apparatus and method of Kasdan in order to improve the accuracy of measuring cell type population changes and soluble factor changes during disease progression and during therapy.

As to claim 60, Dietz et al disclose clinical condition is caused by a disorder selected from the group consisting of atherosclerosis, diabetes viral infection and bacterial infection (column 6, lines 4-25).

Claims 40-44 are similarly analyzed and rejected.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6571117 to Marbach.

US 4741043 to Bacus.

US 5000554 to Gibbs.

US 5428690 to Bacus et al.

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US 5460945 to Springer et al.

US 2003/0022393 to Seul et al.

US 2003/0203507 to Liberti et al.

US 5686309 to Frank et al.

US 5878160 to horiuchi et al.

US 5976786 to Finkel et al.

US 6203487 to Consigny.

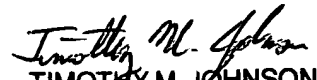
CONTACT INFORMATION

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barry Choobin whose telephone number is 703-306-5787. The examiner can normally be reached on M-F 7:30 AM to 18:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on 703-308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9314.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

Barry Choobin
February 8, 2004


TIMOTHY M. JOHNSON
PRIMARY EXAMINER